



United States  
Department of  
Agriculture

Marketing and  
Regulatory  
Programs

Animal and Plant  
Health Inspection  
Services

Animal Care

920 Main Campus Drive  
Suite 200  
Raleigh, NC 27606

Tel No. 919-855-7100  
Fax No. 919-855-7123

February 2, 2007  
CERTIFIED MAIL  
RETURN RECEIPT  
# 7001 0360 0000 2162 6125

RE: Cust. # 223  
Lic/Reg # 31-R-0017

**Warning Notice**  
APHIS Form 7060

Cleveland Clinic Foundation  
Research Institute  
Bio Research Unit / NC50  
9500 Euclid Ave  
Cleveland, OH 44195

Dear (b)(6), (b)(7)c

The enclosed APHIS Form 7060, "Official Warning, Violation of Federal Regulations," is being issued to you for alleged violations of the Federal Animal Welfare Act. This notice is being issued at this time as a serious warning that if you fail to comply with the requirements of the Animal Welfare Act in the future, this citation and all past and future documented violations will be used to justify a more severe penalty. The Animal Welfare Act provides for penalties of up to \$3,750 per violation. If you have any questions regarding this citation or the Animal Welfare Act, please contact this office at the above address or phone (919) 855-7100.

Sincerely,

Elizabeth Goldentyer, DVM  
Eastern Regional Director  
Animal Care

Enclosure

cc: R. Huttenlocker, IES  
N. Harlan, DVM  
E. Magid, SACS  
K. Carter-Corker, ARD  
OH (223) 31-R-0017



Animal Care is a part of the Department of Agriculture's Animal and Plant Health Inspection Service.

An Equal Opportunity Provider and Employer

**OFFICIAL WARNING**



**VIOLATION OF FEDERAL REGULATIONS**

VIOLATOR

**Customer # 223**  
**Certificate # 31-R-0017**  
**Cleveland Clinic Foundation**  
**Research Institute**

ADDRESS (*Street, City, State, Zip Code*)

**Bio Research Unit / NC 50**  
**9500 Euclid Ave**  
**Cleveland, OH 44915**

The Department of Agriculture has evidence that on or about **January 24, 2007**, you or your organization committed the following violation of Federal Regulations:

**9 CFR, SECTION**

**Failure to**

**2.31 (d)(1)**

- **Have IACUC review activities involving animals. In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing; Provided, however, That field studies as defined in part 1 of this subchapter are exempt from this requirement. Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements.**

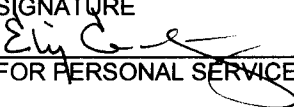
**(There was a procedure conducted on a dog that was not done under an approved protocol. The procedure was done for the training of corporate sales people. The physician ordering the animal utilized an approved research protocol with no training component to request the animal be delivered to the lab. This animal had been purchased from a licensed dealer and had the initial preparatory surgery for the originally intended research protocol. The Doctor diverted the animal to his use for the training program he was conducting.)**

**9 CFR, SECTION****Failure to****2.33 (b)(1)**

- Establish and maintain programs of adequate veterinary care that include the availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of this subchapter

(The surgical area where this procedure took place is extremely cluttered with one very large wood packing crate, a wooden pallet and several cardboard boxes. These are all untreated and not readily cleanable in any way. This does not permit adequate cleaning to allow for sterile technique. There is also a large accumulation of outdated wrapped implements hanging on the wall and stored on the floor in boxes. This increases the clutter and difficulty in cleaning.)

Titles 7 & 9 Code of Federal Regulations were promulgated to help prevent the spread of animal and plant pests and diseases and assure the humane treatment of animals. Since violations of the regulations can have serious and costly impact detrimental to the public interest, you are warned of this violation. Any further violation of these regulations may result in the assessment of a civil penalty or criminal prosecution. If you have any questions concerning this warning or violation, please contact the listed APHIS Official.

APHIS OFFICIAL (Name and Title) <b>Elizabeth Goldentyer, DVM</b> <b>Regional Director</b>		OFFICE ADDRESS: <b>920 Main Campus Dr., Suite 200</b> <b>Raleigh, NC 27606</b> <b>TELEPHONE NO. AC (919) 855-7100</b>
SIGNATURE 	DATE ISSUED <b>2/2/07</b>	DATE RECEIVED:
FOR PERSONAL SERVICE - RECEIVED BY: (Name and signature)		

FOR CERTIFIED MAIL - RECEIPT NO:  
**7001 0360 0000 2162 6125**

APHIS FORM 7060      Previous editions may be used  
(JUN 91)      **PART 1 - VIOLATOR**

JAN 1 4 2007



January 11, 2007

Dr. Ellen Magid  
USDA, Animal Care  
920 Main Campus Drive, Suite 200  
Raleigh, NC 27606

Dear Dr. Magid:

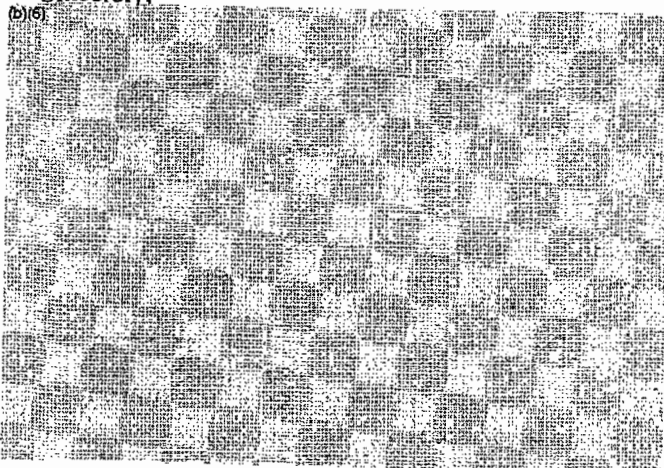
This letter is to inform you of a noncompliance that occurred yesterday at the Cleveland Clinic Lerner Research Institute (A3047-01, USDA # 31-R-0017).

The noncompliance involved an approved protocol using a canine model of cerebral aneurysm. The incident involved one dog. A procedure was performed (intracarotid injection of coils for the purpose of embolization of the experimental aneurysm). Although the creation of the aneurysm model was approved by the IACUC in this protocol, this specific experimental procedure involving injection of coils was not approved. In addition, this procedure was done in a workshop format involving physician training of sales personnel for the commercial sponsor producing the coils. Our IACUC has a policy that workshops involving animals are not approved if it is for the exclusive purpose of training sales personnel. We do approve workshops for physician training for new devices.

The IACUC became aware of this incident when the IACUC Office received a fax that was sent by PETA to the coil manufacturer. A copy of the fax is enclosed. We have been informed by the Media Relations unit at the Cleveland Clinic that PETA has also communicated with The Cleveland Plain Dealer newspaper, and that an article will be published in the January 12 morning edition.

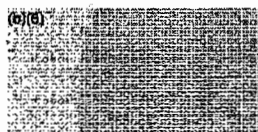
Our institution is committed to take appropriate action concerning the investigators involved in this incident. The CEO, the Chief-of-Staff and the Office of the General Counsel have all played an active role in assessing this situation over the last 24 hours. I will send you a follow-up letter informing you of the corrective actions that will be taken.

Sincerely,





JAN 22 2007



January 19, 2007

Dr. Ellen Magid  
USDA, Animal Care  
920 Main Campus Drive, Suite 200  
Raleigh, NC 27606

Dear Dr. Magid:

This is a follow-up to the letter that I sent to you on January 11, 2007 concerning a protocol noncompliance that occurred on January 10, 2007 at the Cleveland Clinic Lerner Research Institute (A3047-01, USDA # 31-R-0017).

The IACUC convened a meeting to discuss the noncompliance on January 18, 2007. A quorum of the IACUC was present. After lengthy discussion, the IACUC unanimously recommended to me in my capacity as the Institutional Official, the following corrective measures:

1. The investigator directly responsible for the noncompliance will not be allowed to perform research involving animals for a period of two years starting from the date of the noncompliance.
2. All investigators involved in endovascular research will be required to complete a rigorous retraining program before they will be allowed to perform animal research.
3. The endovascular research group will be required to develop a formal internal set of guidelines involving animal research. This will include internal checks and balances designed to prevent a future noncompliance.

In addition to these corrective actions recommended by the IACUC, the Institution has delineated additional corrective measures to reflect the seriousness by which the Institution has viewed this noncompliance. I would be happy to provide any additional information that you might require regarding this issue.

Sincerely,





## INSPECTION REPORT

CLEVELAND CLINIC FOUNDATION  
RESEARCH INSTITUTE

Customer ID: 223

Certificate: 31-R-0017

Site: 001

CLEVELAND CLINIC

BIO RESRC UNIT/NC50, 9500 EUCLID AVE  
CLEVELAND, OH 44195

Inspection

Type: ROUTINE INSPECTION

Date: JAN-24-2007

## 2.31 (d)(1)

## INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(a) IACUC review of activities involving animals.

(1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing; Provided, however, That field studies as defined in part 1 of this subchapter are exempt from this requirement. Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements

There was a procedure conducted on a dog that was not done under an approved protocol. The procedure was done for the training of corporate sales people. The physician ordering the animal utilized an approved research protocol with no training component to request the animal be delivered to the lab. This animal had been purchased from a licensed dealer and had the initial preparatory surgery for the originally intended research protocol. The Doctor diverted the animal to his use for the training program he was conducting. This is a violation of the regulations requiring that all animal usage be conducted under approved protocols following the delineated guidelines set down for research and mandated by law. These guidelines are designed to prevent animal wastage and to protect the animals from unnecessary pain and distress.

The research facility has conducted a thorough investigation and provided an adequate response in both disciplinary actions for this individual and additional training and checks and balances to attempt to prevent any future incidences of this nature.

Corrected

## 2.33 (b)(1)

## ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:

(1) The availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of this subchapter

The surgical area where this procedure took place is extremely cluttered with one very large wood packing crate, a wooden pallet and several cardboard boxes. These are all untreated and not readily cleanable in any way. This does not permit adequate cleaning to allow for sterile technique. There is also a large accumulation of outdated wrapped implements hanging on the wall and stored on the floor in boxes. This increases the clutter and difficulty in cleaning. This does not provide for adequate veterinary care for the animals utilized in this room.

Correct by: next use for animal research

Prepared By:

NORMA JEAN HARLAN, DVM, USDA, APHIS, Animal Care

Title:

Received By:

Title:

Date:

JAN-25-2007

Date:

JAN-26-2007



CLEVELAND CLINIC FOUNDATION  
RESEARCH INSTITUTE

Customer ID: 223

Certificate: 31-R-0017

Site: 001

CLEVELAND CLINIC

BIO RESRC UNIT/NC50, 9500 EUCLID AVE  
CLEVELAND, OH 44195

Inspection

Type: ROUTINE INSPECTION

Date: MAY-31-2008

### 2.31 (d)(1)(ii)

#### INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(ii) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources, e. g., the Animal Welfare Information Center, used to determine that alternatives were not available;

The section in the protocols for determining whether there were any alternatives to painful procedures did not adequately address the point in the following protocols: pigs - ARC#s 00766, 07493, dog - Arc #s 07349, 07627, 07438, 07906, primate - Arc#s 007481, 07748, Rabbit - Arc# 07739.

On all of these protocols only one search engine was used to search for alternatives to Painful Procedures. To conduct an adequate search and be sure that all reasonable possibilities are covered at least two different search engines should be used. They should be selected based on the topic to be researched. If a literature search is not available than an appropriate alternative must be used and documented.

This must be properly done to assure that all possible care is being taken to provide for the animals health and well being. All protocols must be checked, not just the ones that I have identified in this write up.

Note: the more recent protocols now use two search engines in their search strategy, it is just the older protocols that have this problem.

Correct by: 7/1/08

### 3.11 (c)

#### CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.

(c) Housekeeping for premises. Premises where housing facilities are located, including buildings and surrounding grounds, must be kept clean and in good repair to protect the animals from injury, to facilitate the husbandry practices required in this subpart, and to reduce or eliminate breeding and living areas for rodents and other pests and vermin. Premises must be kept free of accumulations of trash, junk, waste products, and discarded matter. Weeds, grasses, and bushes must be controlled so as to facilitate cleaning of the premises and pest control, and to protect the health and well-being of the animals.

Clutter in the surgical rooms and hallway. There was an excessive buildup of clutter in the hallways in the main operating room areas. This needs removed to permit adequate husbandry and prevent potential problems with pests. This is for the health and well being of the animals.

Correct by: 6/21/08

There was a pile of clutter on the floor in one surgery room during a non survival procedure on a pig. There was a table that could have been used to hold these supplies in one corner that was completely empty. These items need to be off the floor

Prepared By:

*Norma Jean Harlan*

NORMA JEAN HARLAN, D V M , USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER, Inspector ID: 1004

Received By:

Title:

Date:

MAY-31-2008

Date:

MAY-31-2008



United States Department of Agriculture  
Animal and Plant Health Inspection Service

NHARLAN



JUN 07 2006 223 cust\_id  
44878 insp\_id  
6121 site\_id

for surgical purposes. Non survival procedures for major species must be done in a clean if not sterile manner.  
Correct by: 6/6/06

Left a copy of Policy 12, Consideration of Alternatives to Painful/ Distressful Procedures

Prepared By:

*Norma Jean Harlan DVM*

NORMA JEAN HARLAN, D V M , USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER Inspector ID: 1004

Received By:

Title:

Date:

MAY-31-2006

Date:

MAY-31-2006





United States Department of Agriculture  
Animal and Plant Health Inspection Service

NHARLAN

INSPECTION REPORT

FEB 06 2006

223 cust\_id  
144804 insp\_id  
9925 site\_id

CLEVELAND CLINIC FOUNDATION  
RESEARCH INSTITUTE

Customer ID: 223  
Certificate: 31-R-0017

BIO RESRC UNIT/NC50, 9500 EUCLID AVE  
CLEVELAND, OH 44195

Site: 003  
NORTHEAST OHIO UNIVERSITY

Inspection  
Type: ROUTINE INSPECTION  
Date: JAN-31-2006

No animals present during this inspection. No noncompliant items identified during this inspection.

Prepared By:

*Norma Jean Harlan*

NORMA JEAN HARLAN, D V M , USDA, APHIS, Animal Care

Title:

VETERINARY MEDICAL OFFICER

Received By:

Title:

Date:

JAN-31-2006

Date:

JAN-31-2006



JUN 29 2005

NRHARLAN

223 cust\_id

144677 insp\_id

6121 site\_id

**INSPECTION REPORT**

**CLEVELAND CLINIC FOUNDATION  
RESEARCH INSTITUTE**

Customer ID: 223

Certificate: 31-R-0017

Site: 001

CLEVELAND CLINIC

Inspection

Type: ROUTINE INSPECTION

Date: JUN-20-2005

**BIOLOGICAL RESOURCES UNIT/NC50  
9500 EUCLID AVE  
CLEVELAND, OH 44195**

**2.31 (d) REPEAT NCI  
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).**

(5) The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, but not less than annually

In 2003, 2004, and now 2005 the Cleveland Clinic IACUC reported errors in the annual review of their animal use protocols. This time it was protocol (b)(6) that should have been reviewed the end of August, 2004. This oversight was not noted until May, 2005. The necessary review information was not received until 5/16/05. The researcher claimed at the time that it was a duplicate of information sent prior to the end of August, 2004. There was one difficulty with the accuracy of that observation. The animals listed on the report were not received until mid September. The report itself was signed 5/16/05. Continuing ongoing reviews must be conducted at least annually of all animal activity. This is to maintain adequate control of ongoing research activities by the IACUC, to prevent animal harm, loss, or wastage.

REMAINS UNCORRECTED

Note, the following corrections are being implemented to prevent any reoccurrences of this incident:

- 1) A 90, 60, and 30 day reminder is being sent to each researcher in advance of the annual renewal information being required.
- 2) The first day of the month following the due date for their renewal the researcher is notified that no further activity is to occur until such time as they have contacted the IACUC and corrected this problem. When this notice goes up, salmon colored animal ID cards are placed on the animals, identifying them as belonging to the facility protocol. The caretakers will be monitoring for any unauthorized activity.
- 3) Taking too long to rectify the situation could result in the requirement to rewrite the entire protocol and pursue full IACUC approval.

One last item to be implemented is to check for the status of the protocol prior to the arrival of the animals. It is presently being checked at the time of ordering, but some orders take long enough that this status changes in between.

Prepared By:

*Norma Jean Harlan*  
NORMA JEAN HARLAN, DVM, USDA, APHIS, Animal Care

Title:

(b)(6), (b)(7)(c) Director ID: 1004

Received By:

Title:

Date:

JUN-20-2005

Date:

JUN-20-2005

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.  
31-R-0017

CUSTOMER NO.  
223

FORM APPROVED  
OMB NO. 0579-0036

# ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

CLEVELAND CLINIC FOUNDATION  
BIO RESRC UNIT/NC50, 9500 EUCLID AVE  
CLEVELAND, OH 44195

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

## FACILITY LOCATIONS (sites)

CLEVELAND CLINIC  
CLEVELAND, OH 44195

DALWOOD FARMS  
WAKEMAN, OH 44889

COLLEGE OF MEDICINE  
ROOTSTOWN, OH 44195

NAMSA  
NORTHWOOD, OH 43619

## REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS  (Cols. C + D + E)
4. Dogs	7		360		360
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits			189		189
9. Non-Human Primates	9	2	6		8
10. Sheep	1		11		11
11. Pigs			209		209
12. Other Farm Animals					
calves			14		14
13. Other Animals					

## ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

## CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

11/13/2008

DEC 06 2006

31817  
C#223

THE CLEVELAND CLINIC  
FOUNDATION



LERNER RESEARCH INSTITUTE



November 30, 2006

United States Department of Agriculture  
920 Main Campus Drive, Suite 200  
Raleigh, NC 27606-5213  
Registration No. 31-R-0017/223

The Cleveland Clinic submitted the FY2006 APHIS FORM 7023 and 7023A electronically on November 30, 2006. We would like to add one exception to the housing standards of the Animal Welfare Act that was reviewed and approved by the IACUC.

Animal Husbandry

Calves with implanted cardiac medical devices are maintained in pens smaller than the standards listed in the Guide for the Care and Use of Laboratory Animals.

Thank you very much,



This report is required by law (7 USC 2143). Failure to file, according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2143.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.  
31-R-0017

CUSTOMER NO.  
222

FORM APPROVED  
OMB NO. 0579-0038

## ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

CLEVELAND CLINIC FOUNDATION  
BIO RESRC UNIT/NC50, 9600 EUCLID AVE  
CLEVELAND, OH 44195

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, teaching, learning, or experimentation, or held for those purposes. Attach additional sheets if necessary.)

### FACILITY LOCATIONS (Name)

CLEVELAND CLINIC  
CLEVELAND, OH 44195

DALWOOD FARMS  
WAKEMAN, OH 44889

COLLEGE OF MEDICINE  
ROOTSTOWN, OH 44195

RAVENS GLENN FARM  
PLASKI, PA 16143

### REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, learning, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetics, analgesics, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetics, analgesics, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NO. OF ANIMALS (Data C + D + E)
4. Dogs	13		340		340
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	3		361		361
9. Non-Human Primates	4	9	12		21
10. Sheep	1	1	12		13
11. Pigs	5		114		114
12. Other Farm Animals					
calves	1		32		32
13. Other Animals					

### ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetics, analgesics, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and if any exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report, in addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

### CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL (Chief Executive Officer or Legally Responsible Institutional official) (I certify that the above is true, correct, and complete (7 U.S.C. Section 2143))

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

10/12/2005

APHIS FORM 7023  
(AUG 91)

(Replaces VS FORM 16-23 (Oct 86), which is obsolete)

PART 1 - HEADQUARTERS

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.  
31-R-0017

CUSTOMER NO.  
223

FORM APPROVED  
OMB NO. 0579-0038

# ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include ZIP Code)

CLEVELAND CLINIC FOUNDATION  
BIOLOGICAL RESOURCES UNIT/FFB-04  
9500 EUCLID AVE  
CLEVELAND, OH 44115

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for those purposes. Attach additional sheets if necessary.)

## FACILITY LOCATIONS (List)

COLLEGE OF MEDICINE  
ROOTSTOWN, OH 44185

CLEVELAND CLINIC FOUNDATION  
PULASKI, PA 16143

DALWOOD FARMS  
WAKEMAN, OH 44886

## REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving pain or distress to the animals and for which appropriate analgesic, anesthetic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate analgesic, anesthetic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NO. OF ANIMALS (Cells C + D + E)
4. Dogs	8		355		363
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits		24	286		310
9. Non-Human Primates	9		7		7
10. Sheep			27		27
11. Pigs	2		180		180
12. Other Farm Animals					
goats			6		6
13. Other Animals					

## ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of analgesic, anesthetic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report in addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

## CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

11/30/2004

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 31-R-0017  
CUSTOMER NUMBER: 223

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
(TYPE OR PRINT)

Cleveland Clinic Foundation  
Research Institute  
Biological Resources Unit/NC50  
9500 Euclid Ave  
Cleveland, OH 44195

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (State) - San Antonio, Texas

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7022A)

A. Animals Covered By This Animal Welfare Regulation	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals in for which appropriate anesthesia, analgesia, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthesia, analgesia, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures preceding pain or distress in these animals at the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (COLUMNS C+D+E)
4. Dogs	16		409		409
5. Cats					0
6. Guinea Pigs					0
7. Hamsters			40		40
8. Rabbits		24	134		158
9. Non-human Primates	4	4	5		9
10. Sheep	2		37		37
11. Pigs	1		176		176
12. Other Farm Animals					
13. Goats			10		10
13. Other Animals					
Calves	1		28		28

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATURE: \_\_\_\_\_ NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print): \_\_\_\_\_ DATE SIGNED: 11/29/03



Betty J Goldentyer

01/12/2007 02:38 PM

To: Lesia.M.Banks@aphis.usda.gov

cc:

Subject: # of dogs used in medical research

Lesia,

These numbers include all the dogs reported as having been used in research in any way.

'04 - 65,012

'05 - 66,610

'06 - 49,898

Call me if you need anything else.

Betty